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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/23/2004

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,441

Applicant(s)

MARTIN, ERIC C.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-10, 16-23, 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,824,071 to Nelson in view of US 6,605,053 to Kamm et al. Nelson discloses an apparatus for providing retrograde perfusion via conduit disposed between the left ventricle and the coronary sinus in order to provide transmyocardial infusion. Nelson further discloses a shunt in the form of plug 70 with valve 77 in the coronary ostium that may be deployed percutaneously (see columns 3, 4, 6, FIG 4). Nelson fails to disclose the hourglass shape of the restricting stent. However, Kamm

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discloses a stent that may be of mesh construction with an outer wall for deployment in the myocardium that features a constricted portion in order to provide greater resistance to blood flow in a first direction than a second direction (see column 2, FIG 16A). Kamm discloses that the stents contemplated in his device include varying shape designs that promote passive flow control, including a tapered shape that changes the diameter of the inner lumen of the conduit. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the stents of the Nelson device in an hourglass or tapered shape, as claimed, in order to provide passive flow control, as taught by Kamm.

With regard to applicant's claims drawn to the size of the stent, It would have been obvious to one of ordinary skill in the art at the time of invention to make the stents of an appropriate size for the required application, since both the prior art stents and the instantly claimed invention are directed to the same mode of employment. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable range, including size ranges, involves only routine skill in the art. See MPEP 2144.04, 2144.05.

Furthermore, with regard to the claims drawn to the placement of the stent in the patient, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

5. Claims 11-15, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,824,071 to Nelson in view of US 6,605,053 to Kamm et al, further in view of

US 5,755,682 to Knudson et al. Nelson and Kamm disclose the apparatus as claimed with the exception of varying the location of the outer surface of the stent. Knudson discloses a stent with an inner and outer portion wherein the inner and outer surfaces may be interchanged. FIG 3 shows a number of inner rings 17 enclosed by a membrane 18 (see column 14) in order to provide structural integrity to the device. FIGS 7 and 8 show the stent with reinforcing members illustrated on the outer surface of the stent. Therefore, it would have been obvious to one of ordinary skill in the art to provide the stent disclosed by Nelson and Kamm with inner or outer reinforcing means in order to provide structural strength in the stent, as taught by Knudson.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,027,526 Limon et al
 - i. Stent with varied amount of structural reinforcement
- b. US 6,190,406 Duerig et al
 - ii. Stent with tapered shape


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
6 April 2004



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